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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/503,387	02/14/2000	Samantha J. Busfield	MBIO99-057CP2M	6531

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MILLENNIUM PHARMACEUTICALS INC
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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/503,387

Applicant(s)

BUSFIELD ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29,33-47,53,54,65-79 and 87-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 33-34, 36-39, 41-43, 45-46, 53-54, 65, and 69-79 is/are rejected.
- 7) ☒ Claim(s) 35,40,44,47,66-68 and 87-90 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/17/03 has been entered.
2. Please note that claims 1-23 have been canceled by amendment filed 1/25/01.
3. Claims 26-29, 33-47, 53-54, 65-79 and 87-90 are pending and are being acted upon in this Office Action.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
5. Claims 26-29, 33-34, 36-39, 41-43, 45-46, 53-54, 65, and 69-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear if the polypeptide in claims 26, 27, 29, 33, 34, 71, 74, 78, and 79 to which the claimed antibody or fragment binds is open or close ended. It is suggested that "polypeptide of the amino acid sequence of SEQ ID NO: 3" be recited "...polypeptide comprising the amino acid sequence of SEQ ID NO: 3" if open end is intended.

The recitation of "humanized antibody" in claim 28 has no antecedent basis in base claim 27 because said phrase is not recited in claim 27. It is suggested that claim 27 be recited A substantially purified non-human monoclonal antibody or humanized antibody or fragment thereof which specifically binds to a polypeptide ~~of comprising~~ the amino acid sequence of SEQ ID NO: 3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 to provide antecedent basis for claim 28.

The "antibody is conjugated to a therapeutic moiety" in claim 33 is indefinite and ambiguous because the preamble of claim 33 recites a monoclonal antibody or fragment thereof and not an antibody conjugated to a therapeutic moiety. It is suggested that claim 33 be recited:

A conjugated monoclonal antibody or fragment thereof which specifically binds to a polypeptide ~~of comprising~~ the amino acid sequence of SEQ ID NO: 3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 ~~which~~ wherein the antibody is conjugated to a therapeutic moiety.

The “antibody is linked to a detectable substance” in claim 34 is indefinite and ambiguous because the preamble of claim 34 recites a monoclonal antibody or fragment thereof and not an antibody is linked to a detectable substance. It is suggested that claim 34 be recited: A conjugated monoclonal antibody or fragment thereof which specifically binds to a polypeptide ~~of comprising~~ the amino acid sequence of SEQ ID NO: 3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 ~~which~~ wherein the antibody is ~~linked~~ conjugated to a detectable substance.

The “antibody or fragment does not contain more than 30% of contaminating antibodies directed against epitopes other than those on the TANGO 268 polypeptide” in claim 36 is indefinite and ambiguous because it is not clear what is the relationship between TANGO 268 polypeptide and polypeptide of SEQ ID NO: 3. It is suggested that claim 36 be recited: A substantially purified antibody or a fragment thereof which specifically binds to ~~an~~ the extracellular domain of the amino acid sequence of SEQ ID NO: 3, ~~wherein said antibody or fragment does not contain more than 30% of contaminating antibodies directed against epitopes other than those on the TANGO 268 polypeptide.~~

The “consists of **about** amino acid residues 21 to 269 of SEQ ID NO: 3” in claim 37 is ambiguous and indefinite and one of ordinary skill in the art cannot appraise the metes and bound of the claimed invention because the specific range of amino acid residues designates the extracellular domain. It is suggested that claim 37 be recited: The antibody of claim 36, wherein the extracellular domain consists of ~~about~~ amino acid residues 21 to 269 of SEQ ID NO: 3.

The “comprises” in Claim 38 is ambiguous and indefinite because it is not clear what additional amino acid residues to be included in the extracellular domain. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention. It is suggested that claim 38 be recited: The antibody of claim 38, wherein the extracellular domain ~~comprises~~ consists of an immunoglobulin-like domain.

The “consists of **about** amino acid residues 48 to 88 or 134 to 180 of SEQ ID NO: 3” in claim 39 is ambiguous and indefinite and one of ordinary skill in the art cannot appraise the metes and bound of the claimed invention because the specific range of amino acid residues designates

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the immunoglobulin domain. It is suggested that claim 39 be recited: The antibody of claim 38, wherein the immunoglobulin-like domain consists of ~~about~~ amino acid residues 48 to 88 or 134 to 180 of SEQ ID NO: 3.

The “an extracellular domain” in claims 41-43 is indefinite since there is only one extracellular domain in SEQ ID NO: 3. It is suggested that the word “an” be replaced with “the”.

The “antibody which is conjugated to a therapeutic moiety” of claim 45 has no antecedent basis in base claim 36. Base claim 36 requires only antibody and not conjugated antibody. It is suggested that claim 45 be amended to: A conjugated ~~The~~ antibody of claim 36 which is conjugated to a therapeutic moiety.

Likewise, The “antibody which is linked to a detectable substance” of claim 46 has no antecedent basis in base claim 36. Base claim 36 requires only antibody and not conjugated antibody. It is suggested that claim 46 be amended to: A conjugated antibody of claim 36 ~~which~~ wherein the antibody is ~~linked~~ conjugated to a detectable substance.

The “A kit comprising *an* antibody” in claims 53 and 54 should have been “A kit comprising *the* antibody” in claims 24 and 46, respectively.

The “GPVI” in claim 65 is ambiguous and indefinite because it is not clear what said phrase stands for. Further, “or” is missing between SEQ ID NO: 3 and the amino acid sequence encoded by the cDNA. It is suggested that claim 65 be amended to: A method of making antibody that specifically ~~recognizes~~ binds to glycoprotein VI (GPVI), the method comprising:

- a) immunizing a mammal with a polypeptide comprising the amino acid sequence of SEQ ID NO: 3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180; and
- b) collecting a sample from the mammal that contains an antibody that specifically ~~recognizes~~ binds to GPVI.

The “recognize” in claim 69 should have been “bind to” since the specification does not define the term antibodies recognize”. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The “an extracellular domain” in claim 70 is indefinite since there is only one extracellular domain in SEQ ID NO: 3. It is suggested that the word “an” be replaced with “the”.

The “A monoclonal antibody” in claim 71 is indefinite and ambiguous because it is not clear how monoclonal antibody in the preamble becomes a human antibody, humanized antibody or chimeric antibody at the end. It is suggested that claim 71 be amended to: An ~~monoclonal~~

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antibody or fragment thereof which specifically binds to a polypeptide ~~of comprising~~ the amino acid sequence of SEQ ID NO: 3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody.

The antibody in claim 72 has no antecedent basis in base claim 71. Base claim 71 requires only that the antibody be monoclonal, human, humanized, or chimeric antibody. It is suggested that claim 72 be amended to: A conjugated ~~The~~ antibody of claim 71 which is conjugated to a therapeutic moiety.

Likewise, It is suggested that claim 73 be amended to: A conjugated ~~The~~ antibody of claim 71 ~~which is linked wherein the antibody is conjugated~~ to detectable substance.

The “A monoclonal antibody” in claim 74 is indefinite and ambiguous because it is not clear how monoclonal antibody in the preamble becomes a human antibody, humanized antibody or chimeric antibody at the end linked to a detectable substance. It is suggested that claim 74 be amended to: A conjugated ~~monoclonal~~ antibody or fragment thereof ~~which wherein the antibody~~ is linked to a detectable substance selected from the group consisting of an enzyme, a prosthetic group, a fluorescent material, a luminescent material, a bioluminescent material, and a radioactive material and ~~which~~ specifically binds to a polypeptide ~~of comprising~~ the amino acid sequence of SEQ ID NO: 3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 and wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody.

The “A kit comprising *an* antibody” in claim 75 should have been “A kit comprising *the* antibody” in claim 26, 87, 88, 89 or 90.

The “A kit comprising *an* antibody” in claims 76 and 77 should have been “A kit comprising *the* antibody” in claims 27 and 29, respectively.

The “kit comprising a monoclonal antibody” in claim 78 is indefinite and ambiguous because it is not clear how a kit comprising monoclonal antibody in the preamble becomes a kit comprising human antibody, humanized antibody or chimeric antibody at the end. It is suggested that claim 78 be amended to: A kit comprising an ~~monoclonal~~ antibody or fragment thereof which specifically binds to a polypeptide ~~of comprising~~ the amino acid sequence of SEQ ID NO: 3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody, and instruction for use.

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The “kit comprising a monoclonal antibody in claim 79” is indefinite and ambiguous because it is not clear how a kit comprising monoclonal antibody linked to a detectable substance in the preamble becomes a kit comprising human antibody, humanized antibody or chimeric antibody at the end linked to a detectable substance. It is suggested that claim 79 be amended to: A kit comprising a conjugated monoclonal antibody or fragment thereof which is linked to a detectable substance, and which specifically binds to a) a polypeptide ~~of~~ comprising the amino acid sequence of SEQ ID NO: 3, or b) the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody, and instruction for use.

6. Claims 35, 40, 44, 47, 66-68, and 87-90 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. No claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to “Neon” Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist (customer service) whose telephone number is (703) 872-9305.

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9. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall I. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401. The IFW official Fax number is (703) 872-9306. For After Final, the Fax number is (703) 872-9307.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

November 17, 2003


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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